

AMENDMENTS

In the Claims:

Please replace claims 1, 13, 18, 19, 20, 22, and 23 with the following replacement claims 1, 13, 18, 19, 20, 22, and 23:

C1 sub C1/ 1. (Amended) A thermal adhesion granulation process for preparing direct tableting formulations or aids, comprising the step of subjecting all or part of a mixture comprising:

- (a) from about 5 to about 99 % by weight of one or more diluent excipients and/or from 0 to about 99% by weight of a pharmaceutically-active ingredient;
- (b) from about 1 to about 95 % by weight of a binder excipient; and optionally with,
- (c) from 0 to about 10% by weight of a disintegrant excipient;

to heating at a temperature range of from about 30 to about 130°C under the condition of from about 0.1 to about 20% initial moisture content and/or from about 0.1 to about 20% initial content of a pharmaceutically-acceptable organic solvent in a closed system with mixing until granules form.

C2 sub C2/ 13. (Amended) A process as defined in claim 12, wherein about 90% of the microcrystalline cellulose particles are in the particle size range from about 1 μm to about 125 μm , and the average particle size is from about 10 μm to about 70 μm .

C3 sub C3/ 18. (Amended) A process as defined in claim 1, wherein the binder excipient further contains from 0 to about 10% by weight with respect to the binder of an anticaking agent.

19. (Amended) A process as defined in claim 18, wherein the binder excipient contains from about 0.01 to about 10% by weight with respect to the binder of an anticaking agent.

20. (Amended) A process as defined in claim 18, wherein the binder excipient contains from about 2 to about 4% by weight with respect to the binder of an anticaking agent.

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22. (Amended) A product prepared by the process of claim 1.

23. (Amended) A powder mixture of soluble polyvinyl pyrrolidone containing from about 0.01 to about 10% by weight with respect to the polyvinyl pyrrolidone of dibasic calcium phosphate anhydrous.

Please enter the following new claims 34-58:

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34. (New) A thermal adhesion granulation process, which comprises:

dry-blending binder excipient, one or more diluent excipients, and a pharmaceutically-active ingredient;

adding water and/or a pharmaceutically-acceptable organic solvent to the dry-blended mixture; and

heating at a temperature range from about 30°C to about 130°C with mixing in a closed system until granules form, wherein:

the binder excipient is from about 1% to about 95% by weight,

the one or more diluent excipients are from about 5% to about 99% by weight,

the pharmaceutically-active ingredient is from 0% to about 99% by weight, and

the water and/or the pharmaceutically-acceptable organic solvent is from about 0.1% to about 20% content before heating.

35. (New) The process of claim 34, wherein the mixing is by tumble rotation.

36. (New) A process as defined in claim 34, wherein the temperature range is from about 40 to about 110°C.

37. (New) A process as defined in claim 34, wherein the temperature range is from about 60 to about 105°C.

38. (New) A process as defined in claim 34, wherein the initial moisture content is from about 2 to about 15%.

39. (New) A process as defined in claim 34, wherein the initial moisture content is from about 4 to about 10%.

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40. (New) A process as defined in claim 34, wherein the initial organic solvent content is from about 0.1 to about 10%.

41. (New) A process as defined in claim 34, where the initial organic solvent content is from about 0.5 to about 5%.

42. (New) A process as defined in claim 34, wherein the diluent excipient is powdered cellulose, microcrystalline cellulose, lactose, starch, or dibasic calcium phosphate.

43. (New) A process as defined in claim 34, wherein the pharmaceutically-active ingredient is acetaminophen or ascorbic acid.

44. (New) A process as defined in claim 34, wherein the binder excipient is soluble polyvinyl pyrrolidone or hydroxypropylcellulose.

45. (New) The process of claim 34, wherein a disintegrant excipient is included in the dry-blending step.

46. (New) A process as defined in claim 45, wherein the disintegrant excipient is crospovidone, sodium starch glycolate, reticulated carboxymethylcellulose, or low-substituted hydroxypropylcellulose.

47. (New) A process as defined in claim 34, wherein the diluent excipient is microcrystalline cellulose.

49. (New) A process as defined in claim 47, wherein about 90% of the microcrystalline cellulose particles are in the range from about 1 μm to about 125 μm , and the average particle size is from about 10 μm to about 70 μm .

50. (New) A process as defined in claim 50, wherein the binder excipient is soluble polyvinyl pyrrolidone.

51. (New) A process as defined in claim 50, wherein the soluble polyvinyl pyrrolidone has a K value of from about 12 to about 120.

52. (New) A process as defined in claim 50, wherein the soluble polyvinyl pyrrolidone has a K value of from about 20 to about 95.

53. (New) A process as defined in claim 34, wherein the soluble polyvinyl pyrrolidone has a K value of from about 25 to about 35.

54. (New) A process as defined in claim 34, wherein the binder excipient further contains from 0 to about 10% by weight with respect to the binder of an anticaking agent.

55. (New) A process as defined in claim 34, wherein the binder excipient contains from about 0.01 to about 10% by weight with respect to the binder of an anticaking agent.

56. (New) A process as defined in claim 34, wherein the binder excipient contains from about 2 to about 4% by weight with respect to the binder of an anticaking agent.

57. (New) A product prepared by the process of claim 34.

58. (New) A tablet comprising the product of claim 34.

59. (New) A capsule comprising the product of claim 34.

60. (New) A pellet comprising the product of claim 34.

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61. (New) The process of claim 1, wherein the mixing is by tumble rotation.
